

JAMES A. McDEVITT
United States Attorney
Eastern District of Washington
SHAWN N. ANDERSON
Assistant United States Attorney
402 East Yakima Avenue, Suite 210
Yakima, Washington 98901

FILED IN THE
U.S. DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

NOV 20 2007

JAMES R. LARSEN, CLERK
DEPUTY
RICHLAND, WASHINGTON

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON**

UNITED STATES OF AMERICA,

Plaintiff,

v.

ANIMAL PHARMACEUTICALS,
INC., a Washington Corporation,

Defendant.

No.: CR-06-2116-EFS-1

PLEA AGREEMENT

Plaintiff United States of America, by and through James A. McDevitt,
United States Attorney, and Shawn N. Anderson, Assistant United States
Attorney, for the Eastern District of Washington, and the Defendant, ANIMAL
PHARMACEUTICALS, INC., and the Defendant's counsel, Ellen M.
McLaughlin, agree to the following Plea Agreement:

1. Guilty Plea and Maximum Statutory Penalties:

ANIMAL PHARMACEUTICALS, INC., agrees to plead guilty to an
Information charging the Defendant with Conspiracy to Misbrand a Drug While
Held for Sale, in violation of 21 U.S.C. § 331(k). The Defendant understands that
this is a Class A misdemeanor which carries a maximum penalty of a fine of not
more than \$200,000.00 and a mandatory \$125.00 special penalty assessment.

1 2. The Court is Not a Party to the Agreement:

2 The Court is not a party to this Plea Agreement and may accept or reject this
3 Plea Agreement. Sentencing is a matter that is solely within the discretion of the
4 Court. The Defendant understands that the Court is under no obligation to accept
5 any recommendations made by the United States and/or by the Defendant; that the
6 Court will obtain an independent report and sentencing recommendation from the
7 U.S. Probation Office; and that the Court may, in its discretion, impose any
8 sentence it deems appropriate up to the statutory maximums stated in this Plea
9 Agreement.
10

11 The Defendant acknowledges that no promises of any type have been made
12 to the Defendant with respect to the sentence the Court will impose in this matter.
13 The Defendant understands that the Court is required to consider the applicable
14 sentencing guideline range, but may depart upward or downward under the
15 appropriate circumstances.
16

17 The Defendant also understands that should the sentencing judge decide not
18 to accept any of the parties' recommendations, that decision is not a basis for
19 withdrawing from this Plea Agreement or a basis for withdrawing this plea of
20 guilty.
21

22 3. Waiver of Constitutional Rights:

23 The Defendant, ANIMAL PHARMACEUTICALS, INC., understands that
24 by entering this plea of guilty the Defendant is knowingly and voluntarily waiving
25 certain constitutional rights, including:

- 26 (a) The right to a jury trial;
27 (b) The right to see, hear and question the witnesses;
28

- (c) The right to remain silent at trial;
- (d) The right to testify at trial;
- (e) The right to compel witnesses to testify.

While the Defendant is waiving certain constitutional rights, the Defendant understands the Defendant retains the right to be assisted through the sentencing and any direct appeal of the conviction and sentence by an attorney. The Defendant also acknowledges that any pretrial motions currently pending before the Court are waived.

4. Elements of the Offense:

The United States and the Defendant agree that in order to convict the Defendant of Conspiracy to Misbrand a Drug While Held for Sale, in violation of 21 U.S.C. § 331(k), the United States would have to prove beyond a reasonable doubt the following elements:

- 1) First, during the time charged in Count 1 of the Information, there was an agreement between two or more persons to misbrand a drug while held for sale;
- 2) Second, the defendant became a member of the conspiracy knowing of at least one of its objects and intending to help accomplish it; and
- 3) Third, one of the members of the conspiracy performed at least one overt act for the purpose of carrying out the conspiracy.

The elements of Misbranding a Drug While Held for Sale are as follows:

First, a person must perform an act with respect to a drug that results in the drug being misbranded; and

Second, the act was done while such drug was held for sale after

1 shipment in interstate commerce.

2 A drug is misbranded if its labeling is false or misleading in any particular.

3 21 U.S.C. § 352(a)

4 21 U.S.C. § 321(k) provides that:

5 The term "label" means a display of written, printed, or graphic matter upon
6 the immediate container of any article; and a requirement made by or under
7 authority of this chapter that any word, statement, or other information
8 appear on the label shall not be considered to be complied with unless such
9 work, statement, or other information also appears on the outside container
or wrapper, if any there be, of the retail package of such article, or is easily
legible through the outside container or wrapper.

10 5. Factual Basis and Statement of Facts:

11 The United States and the Defendant stipulate and agree that the following
12 facts are accurate; that the United States could prove these facts beyond a
13 reasonable doubt at trial; and these facts constitute an adequate factual basis for
14 the Defendant's guilty plea. This statement of facts does not preclude either party
15 from presenting and arguing, for sentencing purposes, additional facts which are
16 relevant to the guideline computation or sentencing, unless otherwise prohibited in
17 this Plea Agreement.
18

19 ANIMAL PHARMACEUTICALS, INC. (API), is a Washington
20 corporation with a main office at 1504 South 36th Avenue in Yakima,
21 Washington. API conducts its business on property at that location that is subject
22 to a lease from OPPORTUNITY, L.L.C., a Washington limited liability company.
23 The two business entities have common shareholders and officers. BRUCE RAY
24 NOYES is the majority shareholder and Chief Executive Officer of API and
25 OPPORTUNITY, L.L.C.
26
27
28

1 Beginning on a date unknown, but by on or about January 1, 2001, and
2 continuing through on or about October 20, 2005, API, through its employees and
3 at the direction of BRUCE RAY NOYES, purchased the animal drug Baytril for
4 distribution to API customers in the Eastern District of Washington, and
5 elsewhere. During this time, API had multiple sources of supply for Baytril,
6 including Bayer Animal Health, the manufacturer of the drug. Each vial of Baytril
7 shipped from Bayer was contained within its own box. Furthermore, the lot
8 number and expiration date on the box matched the lot number and expiration date
9 on the vial of drug contained inside. BRUCE RAY NOYES directed API
10 warehouse employees to separate and save genuine Baytril boxes received from
11 Bayer for later use. API warehouse employees saved boxes in this manner on a
12 regular basis during this time period.

15 API also received a drug that was purported to be Baytril from Valley Vet
16 Supply (VVS) in Calipatria, California. API received the drugs from VVS by
17 commercial interstate carriers United Parcel Service and FedEx. Unlike Baytril
18 received from Bayer, the vials received from VVS were not contained within their
19 own boxes. BRUCE RAY NOYES directed API warehouse employees to place
20 the vials supplied by VVS into Baytril boxes obtained from Bayer prior to delivery
21 to API customers. API warehouse employees inserted the vials into Baytril boxes
22 in this manner on a regular basis throughout this period of time. The lot numbers
23 contained on shipping invoices that accompanied the product matched that
24 indicated on the vial inside of the box. However, the lot number and/or expiration
25 date on the box would not match that found on the vial contained inside. This
26 action resulted in the drugs being misbranded.

1 Based on API sales records, the defendants' accountant determined that the
2 volume of questioned drugs amounted to approximately 2.7 percent of API's gross
3 sales.

4 On October 20, 2005, agents with the Food and Drug Administration (FDA)
5 conducted a search of API's warehouse in Yakima. During the course of the
6 search, warehouse foreperson RICKEY BETSCH showed FDA Special Agent Jim
7 Burkhardt where API kept its animal drugs, including Baytril. Investigators also
8 discovered large quantities of what appeared to be genuine drug vial boxes for
9 Baytril. The boxes were empty.

10 BETSCH stated that NOYES placed all orders for drugs from VVS.
11 BETSCH also noted that NOYES had to approve any sales of those drugs to API
12 customers. BETSCH stated that genuine drug vial boxes were kept in the
13 warehouse so the VVS supplied drugs could be placed in them for shipment to
14 API customers in order to give the drugs a more authentic appearance. BRUCE
15 RAY NOYES denies knowing that the drugs contained within the vials were
16 counterfeit in any manner.

17 All Baytril purchased by API was manufactured outside of the State of
18 Washington.

19 6. The United States Agrees:

20 (a) Dismissal(s):

21 At the time of sentencing, the United states agrees to move to dismiss with
22 prejudice the Second Superseding Indictment against ANIMAL
23 PHARMACEUTICALS, INC., and OPPORTUNITY, L.L.C., in cause numbers
24 CR-06-2116-EFS-1&2.

1 (b) Not to File Additional Charges:

2 The United States Attorney's Office for the Eastern District of Washington
3 agrees not to bring any additional charges against ANIMAL
4 PHARMACEUTICALS, INC., and OPPORTUNITY, L.L.C., based upon
5 information in its possession at the time of this Plea Agreement and arising out of
6 Defendants' conduct involving illegal activity charged in the Second Superseding
7 Indictment, unless the Defendants breach this Plea Agreement any time before or
8 after sentencing.
9

10 7. United States Sentencing Guideline Calculations:

11 The Defendant understands and acknowledges that the United States
12 Sentencing Guidelines (hereinafter "U.S.S.G.") are advisory to this case and that
13 the Court will determine the Defendant's applicable sentencing guideline range at
14 the time of sentencing after consideration of the Presentence Investigation Report,
15 the advisory guideline range and the factors set forth in 18 U.S.C. §3553(a).
16

17 (a) Base Offense Level:

18 The United States and the Defendant agree that the base offense level for
19 Conspiracy to Deliver a Misbranded Drug, in violation of 21 U.S.C. § 331(k), is 6.
20 See U.S.S.G. §2N2.1(a).
21

22 (b) Chapter 8 Guideline Calculations:

23 The United States and the Defendant agree that based upon an offense level
24 of 6, the base fine amount is \$5,000.00. U.S.S.G. §8C2.4(d).

25 The culpability score under U.S.S.G. §8C2.5 should include one point for
26 size of the company at the time the offense was committed, less one point for
27 acceptance of responsibility. A total culpability score of 5 results in a minimum
28

1 fine of \$5,000 and a maximum fine of \$10,000.

2 (c) Criminal History:

3 The United States and the Defendant believe that the Defendant's criminal
4 history category is I. However, the United States and the Defendant also
5 understand that the Defendant's criminal history computation ultimately will be
6 determined by the Court after review of a Presentence Investigative Report. The
7 United States and the Defendant therefore have made no agreement and make no
8 representations as to the criminal history category, which shall be determined after
9 the Presentence Investigative Report is completed.
10

11 9. Departures:

12 There are no aggravating or mitigating factors with respect to the correct
13 calculation of the Sentencing Guidelines. The United States and the Defendant
14 agree that they will not seek either an upward or a downward departure from the
15 applicable Guidelines.
16

17 10. Sentence:

18 (a) Probation

19 The United States and the Defendant agree to recommend a five (5)-year
20 term of probation. U.S.S.G. §8D1.2(a)(2), the termination of which shall be
21 reviewable upon motion of the parties if and when all money owed by the
22 Defendant, pursuant to this agreement, is paid in full. Probation shall be subject to
23 conditions as recommended by United States Probation.
24

25 (b) Fine

26 As a result of the provision for restitution in this agreement, no fine will be
27 recommended.
28

1 11. Mandatory Special Penalty Assessment:

2 The Defendant agrees to pay the \$125 mandatory special penalty assessment
3 to the Clerk of the Court for the Eastern District of Washington, at or before
4 sentencing, pursuant to 18 U.S.C. § 3013 and shall provide a receipt from the
5 Clerk to the United States before sentencing as proof of this payment.
6

7 12. Restitution:

8 The United States and the Defendant agree that, pursuant to 18 U.S.C. §§
9 3663, 3663A and 3664, the Court may order restitution in this matter in amounts
10 and on terms to be determined by the Court.

11 The parties agree, subject to the Court's approval, that the duration of the
12 probation shall be extended to a term of 5 years, to enable the defendant, BRUCE
13 RAY NOYES, and the corporate defendant, ANIMAL PHARMACEUTICALS,
14 INC., to pay into the custody of the Court the sum of \$500,000, total, to be paid
15 jointly and severally until that total is satisfied, without interest. This duration of
16 probation is authorized by 18 U.S.C. 3561(c)(2).
17

18 The parties further agree that, subject to Court approval, the restitution shall
19 be paid monthly, according to the following schedule:
20

21 \$3,000 Each month for the first year.

22 \$5,000 Each month for the second year.

23 \$8,000 Each month for the third year.

24 \$13,833.33 Each month thereafter until the total payments amount to
25 \$500,000.

26 This graduated formula will enable the defendants to recover financially
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28

1 from the limitations and constraints resulting from the investigation and pendency
2 of this case.

3 The parties further agree, subject to the Court's approval, that the said total
4 amount should be \$500,000, pursuant to U.S.C. 3663(a)(3), and that the standard
5 for causation of entitlement to restitution shall be determined by the Court, and
6 shall be broader than harm caused by the criminal conduct to which each
7 defendant has pled guilty herein. It is the intent of the parties that claimants be
8 satisfied in an equitable manner, and, to the extent possible, that they recover for
9 damages equitably, without the need to incur the expense of filing a lawsuit.
10

11 The parties agree that the same \$500,000 shall be the total sum paid jointly
12 as restitution and fine by both of said defendants. Monies, if any, not paid as
13 restitution to claimants shall then be paid as a fine to the United States.
14

15 The parties agree that the enforcement procedures set forth in 18 U.S.C.
16 3664 shall be followed in this case.

17 The Defendant herein, by agreeing to pay the sum of \$500,000 and signing
18 this Plea Agreement, does not intend thereby to admit guilt, beyond the offense
19 conduct admitted herein, or admit any other misconduct for purposes of collateral
20 use in any civil litigation advanced by an adverse party to establish issue
21 preclusion or collateral estoppel.
22

23 13. Additional Violations of Law Can Void Plea Agreement:

24 The Defendant and the United States agree that the United States may at its
25 option and upon written notice to the Defendant, withdraw from this Plea
26 Agreement or modify its recommendation for sentence if, prior to the imposition
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1 of sentence, the Defendant is charged or convicted of any criminal offense
2 whatsoever.

3 14. Appeal Rights:

4 In consideration of the government's recommendations contained in this
5 Plea Agreement, the Defendant waives any right to appeal this conviction and the
6 sentence imposed by the Court. The Defendant also waives any right to
7 collaterally attack this conviction and sentence under 28 U.S.C. § 2255, or any
8 other collateral attack (except for ineffective assistance of counsel based on facts
9 discovered after the plea and sentencing). The Defendant acknowledges that this
10 waiver shall result in the dismissal of any appeal or collateral attack the defendant
11 might file challenging the conviction or sentence in this case. If the Defendant
12 files a notice of appeal, a habeas petition, or other collateral attack,
13 notwithstanding this agreement, the Defendant agrees that this case shall, upon
14 motion of the government, be remanded to the district court to determine whether
15 Defendant is in breach of this agreement and, if so, to permit the government to
16 withdraw from the Plea Agreement.
17

18 15. Integration Clause:

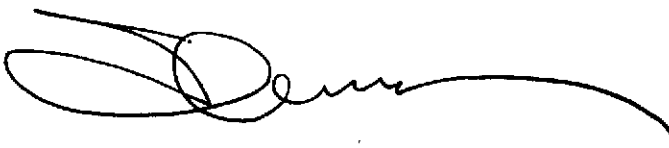
19 The United States and the Defendant acknowledge that this document
20 constitutes the entire Plea Agreement between the United States and the
21 Defendant, and no other promises, agreements, or conditions exist between the
22 United States and the Defendant concerning the resolution of the case. This Plea
23 Agreement is binding only upon the United States Attorney's Office for the
24 Eastern District of Washington, and cannot bind other federal, state or local
25 authorities. The United States and the Defendant agree that this agreement cannot
26
27
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1 be modified except in writing that is signed by the United States and the
2 Defendant.

3 Approvals and Signatures

4 Agreed and submitted on behalf of the United States Attorney's Office for
5 the Eastern District of Washington.

6
7 James A. McDevitt
8 United States Attorney

9 

10
11 SHAWN N. ANDERSON
12 Assistant U.S. Attorney

11/19/07

Date

13 In my capacity as a representative of Animal Pharmaceuticals, Inc., I have
14 read this Plea Agreement and have carefully reviewed and discussed every part of
15 the agreement with my attorney. I understand and voluntarily enter into this Plea
16 Agreement. Furthermore, I have consulted with my attorney about the
17 constitutional rights possessed by Animal Pharmaceuticals, Inc., and I am satisfied
18 with the representation of my attorney in this case. No other promises or
19 inducements have been made to me or Animal Pharmaceuticals, Inc., other than
20 those contained in this Plea Agreement and no one has threatened or forced me in
21 any way to enter into this Plea Agreement. I am agreeing to this plea of guilty
22 because Animal Pharmaceuticals, Inc. is guilty.

23
24 

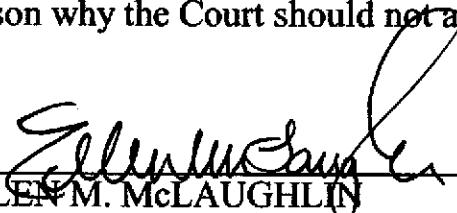
25
26 ANIMAL PHARMACEUTICALS, INC.

11-20-07

Date

27 I have read the Plea Agreement and have discussed the contents of the
28 agreement with my client. The Plea Agreement accurately and completely sets

1 forth the entirety of the agreement between the parties. I concur in my client's
2 decision to plead guilty as set forth in the Plea Agreement. There is no legal
3 reason why the Court should not accept the Defendant's plea of guilty.
4

5
6 
7 ELLEN M. McLAUGHLIN
Attorney for Defendant

11/20/07
Date

8 Approved:

9
10 
11 DONALD E. KRESSE
12 Supervising Assistant U.S. Attorney

11/15/07
Date